



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029

VIA UPS

SEP 26 2016

Mr. Michael R. Faith  
Environmental, Health & Safety Manager  
Jubilant Cadista Pharmaceuticals, Inc.  
207 Kiley Drive  
Salisbury, MD 21808

Re: Request for Information Pursuant to Section 3007(a) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6927(a), Regarding Generation and Management of Hazardous Waste by Jubilant Cadista Pharmaceuticals, Inc.

**Information Request - Reference No. C16-024**  
**EPA ID No. MDR000518225**

Dear Mr. Faith:

The U.S. Environmental Protection Agency, Region III ("EPA") is requesting information to supplement the information obtained during its inspection of Jubilant Cadista Pharmaceuticals, Inc. ("JCP" or "the Facility") located in Salisbury, MD on March 22-23, 2016. EPA is requesting this information pursuant to the authority granted to it under Section 3007(a) of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6927(a), which provides in relevant part that "any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled hazardous wastes shall, upon request of any officer, employee or representative of the Environmental Protection Agency, duly designated by the Administrator, . . . furnish information relating to such wastes . . . ." EPA hereby requires that you furnish to EPA, within **thirty (30) calendar days** of receipt of this letter, the information requested below, including all documents responsive to such request.

For each and every request, if you have any reason to believe that there may be a person(s) who may be able to provide a more detailed or complete response to such request or may be able to provide additional responsive documents, then as a part of your response to such request, identify each such person and the additional information or documents which such person may be able to provide. Furthermore, for each and every response, if information or documents responsive to such request are not in your possession, custody or control, then as part of your response to such request, identify each person from whom such information or documents may be obtained.

Please provide a separate narrative response to each information request. Precede each answer with the number of the question or letter of the subpart of the request to which it corresponds. A request for documents shall be construed as a request for any and all documents maintained by you or in your custody, control, or possession or in the possession, custody or control of any of your employees or agents, relating to the matters described below. All copies of documents submitted to EPA in response to the following requests must be complete and legible.

As used herein, the term “document” means: writings (handwritten, typed or otherwise produced or reproduced) and includes, but is not limited to, any invoices, checks, receipts, bills of lading, weight receipts, toll receipts, correspondence, offers, contracts, agreements, deeds, leases, manifests, licenses, permits, bids, proposals, policies of insurance, logs, books of original entry, minutes of meetings, memoranda, notes, calendar or daily entries, agendas, bulletins, notices, announcements, charts, maps, photographs, drawings, manuals, brochures, reports of scientific study or investigation, schedules, price lists, telegrams, teletypes, phonograph records, magnetic voice or video records, tapes, summaries, magnetic tapes, punch cards, recordings, discs, computer print outs, or other data compilations from which information can be obtained or translated.

All other terms used in this request for information that are defined in RCRA, 42 U.S.C. §§ 6901 *et seq.*, or 40 C.F.R. Parts 260-266 and 268 shall have the meanings set forth therein.

#### Requested Information

1. During the March, 2016 EPA CEI, in the Facility’s Primary Hazardous Waste Accumulation Area (“HWAA”) the EPA inspector observed a container labeled with the words “lab solvent vial waste” and dated as “Dec. 3, 2015.” Please refer to Photo #2 & Photo #3 of the attached EPA CEI Report. Subsequent to the inspection, the Facility provided EPA with manifest #015278566JJK that was dated March 28, 2016, which indicated that the container was sent offsite as hazardous waste. With regard to the container accumulated in the Primary HWAA referenced above, answer the following:
  - a. Provide a detailed description of the process or processes that generated the content(s) of the container, and provide a detailed description of the content(s) of the container.
  - b. Provide the date on which the content(s) of the container was first placed into the container and state the basis of your knowledge. If an exact date cannot be determined, estimate the generation month and year, and explain the basis for such an estimate.
  - c. State the exact date when the container became full. If an exact date cannot be determined, estimate the generation month and year, and explain the basis for such an estimate.
  - d. State the exact date when the container was moved to the Primary HWAA.
  - e. State the volume of the container.
  - f. State the amount (weight and volume) of material in the container at the time of the EPA CEI.



- g. State whether or not a “waste determination” and “LDR determination” was made for the content of the container.
  - h. If a “waste determination” was made for the content of the container, state whether the waste determination was based on analytic results or on the generator’s knowledge of the process that generated the waste. If the determination was based on analytical results, provide any and all documentation of such results. If the determination was based upon the generator’s knowledge, provide a narrative explanation of the scientific basis for each such determination, and provide any supporting documentation.
  - i. Was the contents of the container determined to be “hazardous waste?” If so, state the specific EPA Hazardous Waste Code(s) associated with the contents of the container that was determined to be hazardous waste.
2. During the March, 2016 EPA CEI, the EPA inspector observed six containers of unused and expired CIP 200 and CIP 300 located in the Facility’s Secondary HWAA. Please refer to Photo #4 of the attached EPA CEI Report. Provide the following information regarding the six containers as referenced above in Photo #4:
- a. Provide a detailed description of the process or processes that generated the content of each container, and a detailed description of the content of each container.
  - b. Provide a Material Safety Data Sheet (“MSDS”) and/or SDS for the contents of each container.
  - c. Provide the date on which the content of each container was generated and state the basis of your knowledge. If an exact date cannot be determined, estimate the generation month and year.
  - d. State the exact date when the containers were moved to the Secondary HWAA.
  - e. State the amount (weight and volume) of material in each container at the time of the EPA CEI.
  - f. State whether or not a “waste determination” and “LDR determination” were made for the content of each container.
  - g. If a “waste determination” was made for the content of each container, state whether the waste determination was based on analytic results or on the generator’s knowledge of the process that generated the waste. If the determination was based on analytical results, provide any and all documentation of such results. If the determination was based upon the generator’s knowledge, provide a narrative explanation of the scientific basis for each such determination, and provide any supporting documentation.

- h. Was the content in each container determined to be “hazardous waste?” If so, state the specific EPA Hazardous Waste Code(s) associated with the content of each container that was determined to be hazardous waste.
  - i. If the content of each container was shipped off-site, submit copies of all bills of lading, manifests (hazardous and non-hazardous), shipping invoices, and LDR notices/certifications that accompanied each off-site shipment of the waste.
  - j. If the content of each container still remains on-site, state where such contents are currently located within the Facility and how such contents are currently being managed.
3. During the March, 2016 EPA CEI, in Laboratory 1072 the EPA inspector observed an open beaker labeled with the word “waste” that contained about 200 mL of an unknown substance. Please refer to Photo #10 of the attached EPA CEI Report. With regard to the beaker accumulated in Laboratory 1072, answer the following:
- a. Provide a detailed description of the process or processes that generated the content(s) of the container, and provide a detailed description of the content(s) of the container.
  - b. Provide the date on which the content(s) of the container was first placed into the container and state the basis of your knowledge. If an exact date cannot be determined, estimate the generation month and year, and explain the basis for such an estimate.
  - c. State the volume of the container.
  - d. State the amount (weight and volume) of material in the container at the time of the EPA CEI.
  - e. State whether or not a “waste determination” and “LDR determination” was made for the content of the container.
  - f. If a “waste determination” was made for the content of the container, state whether the waste determination was based on analytic results or on the generator’s knowledge of the process that generated the waste. If the determination was based on analytical results, provide any and all documentation of such results. If the determination was based upon the generator’s knowledge, provide a narrative explanation of the scientific basis for each such determination, and provide any supporting documentation.
  - g. Was the contents of the container determined to be “hazardous waste?” If so, state the specific EPA Hazardous Waste Code(s) associated with the contents of the container that was determined to be hazardous waste.



4. During the March, 2016 EPA CEI, in Laboratory 1073 the EPA inspector observed a closed 5-gallon white bucket labeled as “capped sample vials only” and a 5-gallon yellow bucket labeled as “broken glass only” (Photo #20). According to Facility personnel, the waste sample vials accumulated in the white bucket are managed as hazardous waste, and the broken vials in the yellow bucket is managed as non-hazardous waste. A similar waste management practice for the accumulation of the Facility’s sample vial waste stream was also observed in Laboratory 2009: HPLC Lab (Photo #24) and Laboratory 2006: General Sample Preparation Lab (Photo #26). With regard to the contents of each of the containers (yellow and white) in each of the Laboratories referenced above, answer the following:
- Provide a detailed description of the process or processes that generated the content(s) of the container, and provide a detailed description of the content(s) of the container.
  - State the volume of the container.
  - State the amount (weight and volume) of material in the container at the time of the EPA CEI.
  - State whether or not a “waste determination” and “LDR determination” was made for the content of the container.
  - If a “waste determination” was made for the content of the container, state whether the waste determination was based on analytic results or on the generator’s knowledge of the process that generated the waste. If the determination was based on analytical results, provide any and all documentation of such results. If the determination was based upon the generator’s knowledge, provide a narrative explanation of the scientific basis for each such determination, and provide any supporting documentation.
  - Was the contents of the container determined to be “hazardous waste?” If so, state the specific EPA Hazardous Waste Code(s) associated with the contents of the container that was determined to be hazardous waste.
5. During the March, 2016 EPA CEI, in the Laboratory 2009: HPLC Lab the EPA inspector observed 8 open containers used to accumulate spent material from the HCLP and UCLP machines located in this area of the Facility. Three of the eight containers were documented in Photo #21, Photo #22, & Photo #23 of the attached EPA CEI Report. Based on observations made by the EPA inspector, the containers of HCLP and UCLP waste remain open until they are emptied on a nightly basis into a drum located in Laboratory 1072.
- With respect to the Facility’s HCLP and UCLP waste container management practices, please answer the following:

- i. At the time of EPA's March, 2016 inspection it was the Facility's practice to keep the HCLP and UCLP waste containers open until they are emptied into another container. Has the Facility ever had a different practice with regard to its management of the HPLC and UCLP waste containers? If so, describe such procedures and state the dates during which such procedures were in effect. In addition, please provide the basis of your knowledge.
  - ii. Subsequent to EPA's CEI, did the Facility develop and implement procedures to ensure that the HCLP and UCLP waste containers are closed when waste is not being added or removed? If so, please provide a detailed narrative that explains what the Facility is doing to ensure the HCLP and UCLP containers are closed when waste is not being added or removed.
- b. With respect to the content of the open containers documented in the EPA CEI report in Photo #21, Photo #22, & Photo #23, please answer the following:
  - i. Provide a detailed description of the process or processes that generated the content(s) of the container, and provide a detailed description of the content(s) of the container.
  - ii. State the volume of the container.
  - iii. State the amount (weight and volume) of material in the container at the time of the EPA CEI.
  - iv. State whether or not a "waste determination" and "LDR determination" was made for the content of the container.
  - v. If a "waste determination" was made for the content of the container, state whether the waste determination was based on analytic results or on the generator's knowledge of the process that generated the waste. If the determination was based on analytical results, provide any and all documentation of such results. If the determination was based upon the generator's knowledge, provide a narrative explanation of the scientific basis for each such determination, and provide any supporting documentation.
  - vi. Was the contents of the container determined to be "hazardous waste?" If so, state the specific EPA Hazardous Waste Code(s) associated with the contents of the container that was determined to be hazardous waste.
6. During the March, 2016 EPA CEI, the Facility provided the EPA inspector with a copy of its contingency plan, which was last updated in 2010. Subsequent to the inspection, the Facility indicated in a follow-up letter that it is working with an outside entity to develop



a contingency plan or a comprehensive Spill Prevention Control and Counter Measure Plan. Please submit a copy of the contingency plan and/or Spill Prevention Control and Counter Measure Plan that is currently in effect at the Facility, and indicate the date it was completed and in effect.

7. During the March, 2016 EPA CEI, the EPA inspector reviewed a copy of the Facility's 2015 Biennial Hazardous Waste Report. Indicate by stating "yes" or "no" to the following question: Did the Facility submit a Biennial Hazardous Waste Report for the 2013 calendar year?
  - a. If you answered "yes", provide a copy of the Facility's 2013 Biennial Hazardous Waste Report as an attachment to your response.
  - b. If you answered "no", explain, in detail, why the Facility did not timely submit a Biennial Hazardous Waste Report for the 2013 calendar year.

A copy of the March, 2016 CEI report documenting the findings of the inspector is enclosed as Attachment A for your information, and includes only those attachments not provided by the facility representative(s) at the time of or subsequent to the inspection.

The provisions of Section 3008 of RCRA, 42 U.S.C. § 6928, authorize EPA to pursue penalties for failure to comply with or respond adequately to an information request under Section 3007(a) of RCRA. In addition, providing false, fictitious, or fraudulent statements or representations may subject you to criminal penalties under 18 U.S.C. § 1001. The information you provide may be used by EPA in administrative, civil or criminal proceedings.

With regard to the Small Business Regulatory Enforcement and Fairness Act ("SBREFA"), please see the "Information for Small Businesses" memo, enclosed as Attachment B, which might be applicable to your facility. This enclosure provides information on contacting the SBREFA Ombudsman to comment on federal enforcement and compliance activities and also provides information on compliance assistance. As noted in the enclosure, any decision to participate in such program or to seek compliance assistance does not relieve your Facility of its obligation to respond in a timely manner to an EPA request or other enforcement action, create any rights or defenses under law, and will not affect EPA's decision to pursue an enforcement action. To preserve your Facility's legal rights, you must comply with all rules governing the administrative enforcement process. The Ombudsman and fairness boards do not participate in the resolution of EPA's enforcement actions. EPA has not made a determination as to whether or not your Facility is covered by SBREFA.

Your Facility is entitled to assert a claim of business confidentiality covering any part or all of the information submitted, in a manner described in 40 C.F.R. § 2.203(b). Information subject to a claim of business confidentiality will be made available to the public only in accordance with 40 C.F.R. Part 2, Subpart B. Unless a claim of business confidentiality is asserted at the time the requested information is submitted, EPA may make this information available to the public without further notice to your Facility.

This request for information is not subject to review by the Office of Management and Budget pursuant to the Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520.

Your response must include the following signed and dated certification:

I certify that the information contained in this response to EPA's request for information and the accompanying documents is true, accurate and complete. As to the identified portions of this response for which I cannot personally verify their accuracy, I certify under penalty of law that this response and all attachments were prepared in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

Signature: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Please send your response to:

Andrew Ma  
US EPA Region III  
Environmental Science Center  
701 Mapes Road  
Fort Meade, MD 20755-5350

If you have any questions concerning this matter, please contact Mr. Andrew Ma at (410) 305-3429.

Sincerely,



Carol Amend, Associate Director  
Land and Chemicals Division  
Office of Land Enforcement

Enclosures

cc: A. Ma (3LC70) w/o